DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

DEC 9 2004

Frederick S. Mayer, R.Ph., M.P.H.
Pharmacists Planning Service, Inc. (PPSI)
101 Lucas Valley Road
Suite 210
San Rafael, CA 94903

Re: Docket No. 2004P-0315
Comment No. CP1

Dear Mr. Mayer:

This is in reference to your citizen petition (CP1) dated June 23, 2004, filed under Docket No. 2004P-0315 in the Division of Dockets Management. The petition requests that the Commissioner of FDA switch pseudoephedrine from over-the-counter sales to Pharmacists-Only class of drugs with mandatory consultation, patient history review, identification, and registration.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, as FDA resources and priorities permit (see 21 CFR 10.30(e)). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because other priorities exist, FDA is unable to provide a response to the petition at this time. We will respond to your petition as soon as we have made a decision on your request.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Steven K. Galson, M.D., M.P.H.
Acting Center Director
Center for Drug Evaluation and Research